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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,442	01/21/2004	John A. Krueger	SPEC-6203	5176

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EXAMINER

JOHNSON, JERROLD D

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/762,442

Applicant(s)

KRUEGER ET AL.

Examiner

Jerrold Johnson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 20-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>26 July 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a surgical cement preparation system, classified in class 206, subclass 571.
- II. Claims 20-34, drawn to process for preparing an opacified surgical cement, classified in class 366, subclass 189.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as mixing the ingredients in the mixing vial with the spatula.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Andrew Rodzycki on 05/04/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19.

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Affirmation of this election must be made by applicant in replying to this Office action.

Claims 20-34 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

Claim 19 is objected to because of the following informalities: Claim 19 depends from itself. Appropriate correction is required.

There are two claims numbered 13. Second claim 13 is neither set forth as an independent claim or a dependent claim. Both claims have been examined, despite these errors. Correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1,7,8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160.

Chan discloses a surgical cement preparation system for combining a liquid ingredient together with at least one powder ingredient comprising:

a needle and syringe assembly 275, wherein said needle is structured to couple to said syringe and comprises a closed distal tip and at least one lateral opening located at the distal end of said needle col. 6 lines 12-15 which describes a cannula of the type commonly used to inflate balls, which are known to comprise lateral openings; and

a mixing vial 10, said mixing vial comprising a removable cap 270 structured to sealably close the end of said mixing vial and said cap further comprising a second opening therethrough and a second cap 80 structured to sealably close said second opening.

Chan inferentially discloses the lateral openings in the distal end of the needle by way of his example, but does not explicitly disclose this structure. Fogdog sports

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provides extrinsic evidence (i.e. this reference is for evidence only, it is not applied against the claim) that inflation needles commonly include lateral openings. Ronk explicitly discloses the needle structure with lateral openings for the passage of a liquid surgical cement component into a powdered component. The benefits of this teaching are known to be better distribution of the liquid within the powder, and for this reason it would have been obvious to one of ordinary skill in the art to provide Chan with this explicit teaching.

Additionally, although Chan discloses a cap 80 over a second opening in the removable cap 270, Chan does not explicitly set forth that the cap is removable. However, a removable cap would be an equivalent structure to the cap 80 to those of ordinary skill in this art. For that reason, it would have been obvious to have used a removable cap in place of the cap 80 within the invention of Chan.

Howson explicitly sets forth a cap 45 on a second opening in a removable cap. The opening that is closed by the cap 45 is used for the insertion of a syringe.

Accordingly, from the teachings of Howson, it would also have been obvious to one of ordinary skill in the art to provide removable cap for the second opening in the cap of Chan. The cap as taught by Howson would provide the same benefits as the cap currently used in Chan, i.e. minimize fumes, allow a vacuum to be created in the vial, and permit a syringe needle to extend into the vial therethrough. However, a removable cap would not be subject to damage or deterioration from use, as would the cap 80 currently used by Chan which could be damaged when a needle is passed through it.

Re claim 7, Howson discloses a plurality of lateral openings.

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Re claim 8, the syringe of Chan includes a plunger (piston 300).

Re claim 10, the second opening is dimensioned to accommodate insertion of the needle.

2. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160, as applied above, and further in view of Miller et al. US 6,783,515.

Re claim 9, Miller discloses polypropylene in a surgical cement applicator in col. 9, line 52. Polypropylene is well known in this art for its compatibility with the chemicals in PMMA surgical cement.

Accordingly, it would have been obvious to one of ordinary skill in the art to use polypropylene in the syringe components.

3. Claims 2,5,6,11-13 (first occurrence), and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160, as applied above, and further in view of Bonitati et al. US 5,586,821, Harrod US 4,526,303, Porter US 3,211,195 and Hughes et al. US 6,364,519.

Again, Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160 discloses the needle and syringe and the mixing vial as claimed. Chan further discloses the vial 210 dimensioned to accommodate the liquid component of the cement.

Neither Chan nor Howson or Ronk disclose a funnel or spatula. Chan, does however, disclose in col. 4, lines 44-46 mixing the cement in his mixing vial, and then transferring the mixed cement into a applicator (not shown). He does not disclose the use of a funnel in this process.

Funnels are well known in this art for the administering of the cement ingredients into a mixing chamber, for the administering of mixed cement into the chamber of an applicator, and for the administering of ingredients into a mixing chamber when the mixing chamber is also the cement chamber of an applicator.

Bonitati et al. US 5,586,821 discloses a kit including a funnel 90 for administering of the cement ingredients into a mixing chamber. Harrod US 4,526,303 discloses a funnel 29 for the administering of mixed cement into the chamber of an applicator. Solomon, for the purposes of extrinsic evidence, discloses a funnel 18 for administering the ingredients into a mixing chamber when the mixing chamber is also the cement chamber of an applicator.

It is recognized that neither Bonitati nor Harrod disclose the use of a single funnel for both purposes.

Porter US 3,211,195 discloses how a single funnel 1 is designed to be compatible with a variety of container opening sizes.

Accordingly, as it is known to use a funnel for administering cement ingredients into a mixing chamber (Bonitati), and as it is known for administering mixed cement into the chamber of an applicator (Harrod), and as it is further known to use a single funnel having a structure to mate securely with different sized containers, it would have been

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obvious to one of ordinary skill in the art to have provided a single funnel such as that disclosed by Porter to the invention of Chan to facilitate the administering of the cement ingredients into the mixing vial 10 and then to facilitate the administering of the mixed cement into an applicator.

Regarding the first vial dimensioned to completely accommodate a liquid ingredient container (the liquid monomer) within, Hughes et al. US 6,364,519 discloses providing a first vial 10 dimensioned to completely accommodate a liquid ingredient container (the liquid monomer).

Accordingly, it would further have been obvious to one of ordinary skill in the art to provide the monomer liquid vial in a first vial so as to protect the fragile monomer vial prior to insertion into the syringe of Chan.

Re claim 5, Hughes discloses the first vial comprising a container 30 having a removable cap 18.

Although not claimed explicitly in claim 5, a container disclosing a cap which can be *reinstalled* on the container is not disclosed by Hughes, nor the other cited references, for accommodating a liquid monomer vial.

However, the Examiner takes Official Notice that providing fragile vials in containers having removable caps is common to ensure against breakage of the vials. For example, pharmacists commonly do this when supplying prescriptions of epinephrine in vial form. Accordingly, it also would have been obvious to provide the monomer vial in a container having a removable cap (like a pill container) so that the

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vial is properly protected in transit, it further would be obvious for this container to be compatible with monomer liquid in case the vial breaks accidentally.

Re claim 6, Hughes inherently discloses that the first vial is compatible with the liquid monomer. This is evidenced by the fact that the liquid monomer and the powder can be mixed within the first vial.

Re claims 11-13 (first occurrence), Porter discloses this arrangement.

Re claim 15, Bonitati disclose a tray.

Re claim 16, Chan discloses a pre-filled liquid in a vial, and Bonitati discloses pre-filled liquid in a vial 12.

Re claim 17, Bonitati (14) discloses pre-filled containers with powder ingredients.

Re claim 18, Chan discloses the powdered ingredient in the mixing vial.

4. Claims 3,4,13 (second occurrence), 14 and 19, are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan US 6,516,977 in view of Howson et al. US 4,834,152 and Ronk US 5,951,160, as applied above, and further in view of Bonitati et al. US 5,586,821, Harrod US 4,526,303, and Porter US 3,211,195, as applied above, and further in view of Murphy US 6,273,916.

Re claim 3 and 4, the claimed ingredients of the surgical cement are disclosed within the aforementioned references, as well as within Murphy US 6,273,916. Murphy further describes the use of barium as an opacifier in col. 5 and 6. The Examiner takes Official Notice that barium sulfate, the common form of barium within PMMA surgical cement, is well known in this art and is commonly used to assist in imagery.

Accordingly, it would have been obvious to have included a barium sulfate opacifier in the surgical cement so that the cement could be imaged properly both during and after surgery.

Re claims 13 (second occurrence) and 14, the mixing of surgical cement is known to involve the use of a spatula. The spatulas are also known to be used when transferring the mixed cement to an applicator. Additionally, spatulas are generally well known to be used with mixed ingredients of all types when transferring the ingredients to another container, such as is commonly done while baking.

Murphy US 6,273,916 explicitly discloses a kit including a spatula 88 and 108. The spatula is of a small size that would be suitable for the intended use set forth in claim 13 (second occurrence), as it would clearly be sufficiently small to fit within almost any funnel. Murphy discloses the structure of the spatula set forth in claim 14.

Accordingly, it would have been obvious to one of ordinary skill in the art to provide the spatula of Murphy to manually assist in any mixing that must be performed as well as to assist in the administering of the cement into the funnel while loading the cement applicator.

Re claim 19, although Chan does disclose a powdered ingredient within his mixing vial, Chan does not disclose an opacifier within his powdered ingredients. Murphy discloses the common use of opacifiers within surgical cement to permit imaging of the surgical cement.

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Accordingly, it would have been obvious to have pre-filled the mixing vial of Chan with an opacifier so as to increase the speed at which the loading of the mixing vial with ingredients is performed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ



Mickey Yu
Supervisory Patent Examiner
Group 3700

